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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,499	07/26/2001	David Hung	05284.00096	6261
38732	7590	08/15/2005	EXAMINER	
CYTYC CORPORATION 250 CAMPUS DRIVE MARLBOROUGH, MA 01752			SIRMONS, KEVIN C	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/912,499

Applicant(s)

HUNG, DAVID

Examiner

Kevin C. Sirmons

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 12, 13, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 12, 13, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 12 and 13 rejected under 35 U.S.C. 102(b) as being anticipated by Pestes et al U.S. Pat. No. 5,623,942.

Pestes discloses a flexible probe (12) having a diameter sized to access a breast duct (12) and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis (distal end of 10), and wherein said probe is free of an opening through which a fluid from an external source can be introduced into said probe and pass through said probe into the duct when said probe is positioned within the breast duct (fig. 1), and wherein said probe is rigid before entry into the breast duct, and flexible upon resistance into the duct (col. 2, lines 16-25 and 32-40); as to claims 2-6, (distal end of 10). As to claim 13, (nylon).

Note: Hung et al U.S. Pat. No. 6,391,026 is being used as evidence to support the examiner position that Pestes discloses a flexible probe having a diameter sized to access a breast duct and a distal portion capable of contacting an interior lumen of a breast duct. Hung discloses a catheter suitable for accessing ductal lumens with a distal tip having a outer diameter of about 0.8 mm or 0.08 cm. Pestes discloses the

same diameter of 0.08 cm (emphasis added). Therefore, it is quite clear that the device of Pestes is capable of performing the function as set forth in claim 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-8, 10, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pestes U.S. Pat. No. 5,623,942 in view of Nicholson et al U.S. Pat. No. 4,616,656.

Pestes discloses a device for collecting breast duct fluid substantially as claimed except for a means (marker/indicia) to measure a quality of the ductal fluid in situ.

Nicholson et al discloses a means (marker/indicia) to measure a quality of the ductal fluid in situ (col. 4. lines 12-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal portion of Pestes with the means to measure a quality of the ductal fluid as taught by Nicholson for providing markings to indicate the depth of the device distal end when anchored.

Note: applicant indicates that his quality/means can comprise a marker (page 4, line (8)).

Pestes discloses a device for collecting breast duct fluid substantially as claimed except for a probe diameter between 0.008 cm to about 0.045 cm. Pestes discloses a probe with a diameter 0.08 cm.

It would have been an obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to have various diameter of the probe, since it has been held that such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. Furthermore, applicant has not disclosed that the various diameters solves any stated problem in the art or is for any particular purpose and it appears that the invention of Pestes would perform equally well.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pestes U.S. Pat. No. 5,623,942 in view of Marchosky et al U.S. Pat. No. 4,947,842.

Pestes discloses the device substantially as claimed except for a coating of an anesthetic on the exterior of the probe. Marchosky discloses an anesthetic coating on the exterior of the probe. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Pestes with the coating as taught by Marchosky to relieve pain in the treatment of tumors particularly in the area of the breast (col. 5).

### ***Response to Arguments***

Applicant's arguments filed 7/28/05 have been fully considered but they are not persuasive.

As to claims 1 and 12, it is the examiner position that the probe of Pestes is rigid before entry into the breast duct because it will not unnecessarily bend before entry into

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the breast and yet it is ductile upon resistance to the duct. In conclusion, the device of Pestes is rigid and flexible depending on the environment (col. 2, lines 16-25 and 32-40), which is the same as what is indicated in the above rejection.

Note: Rigid and flexible are relative/broad terms. All of the materials disclosed in Pestes and in applicant's specification can have varying degrees of rigidity and flexibility. Pestes clearly discloses that his device is both flexible (ductile) and rigid (stiff). Applicant has failed to indicate to what degree of rigidity and what degree of flexibility. Therefore, the prior can be anywhere in between.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a **material** that is rigid in one state and flexible upon entry into a breast duct) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As to claims 7, 8, 10, 26 and 27, the marker described in Nicholson et al because his (marker/indicia) can be used on Pestes for measuring size just as applicant has disclosed and suggested in his arguments.

Note: Patent numbers 4,767,011 and 5,003,905 are being provided to clearly show that fiberglass is flexible although one of ordinary skill in the art would clearly know that one could make fiberglass highly flexible or rigid.

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Patent Numbers 6,319,267 and 6,101,635 are being provided to clearly show that nylon is flexible although one of ordinary skill in the art would clearly know that one can make nylon highly flexible or rigid.

### ***Conclusion***

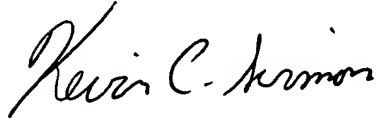
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 571-272-4965. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin C. Sirmons  
Primary Examiner  
Art Unit 3763

A handwritten signature in black ink, reading "Kevin C. Sirmons". The signature is written in a cursive style with a large, stylized "K" and "S".